UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,949	07/10/2003	Lynn Kirkpatrick	126387.0120	4473

7590 09/19/2008

Pepper Hamilton LLP
One Mellon Center
50th Floor
500 Grant Street
Pittsburgh, PA 15219

EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/617,949	KIRKPATRICK ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 August 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: *NONE*.
Claim(s) objected to: _____.
Claim(s) rejected: *1-4,8,9 and 28*.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See page 2.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Continuation of 11: Applicant's arguments have been fully considered but are unpersuasive in view of not entered proposed amendment, as discussed in the Final Rejection, and those found below. All the rejections made in the final office action are MAINTAINED.

Applicant argues that " Halperin fails to even disclose an example of an imidazole in a sustained release delivery system, and obviously fails to disclose an example of an imidazole in a sustained release delivery system that contains a polymer matrix. Accordingly without a specific teaching that asymmetric disulfides, and particularly 1-methylpropyl 2-imidazolyl disulfide, could be formulated into a sustained release delivery composition, there is no reasonable expectation of success in view of the highly unpredictable nature of the art." These arguments have been considered, but not found persuasive. Halperin et al. broadly teaches that active agents that inhibit cancer cell proliferation which include imidazoles compounds can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. Thus even though Halperin et al. does not exemplify asymmetric disulfides, it has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792,794,215 USPQ, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). One of ordinary skill in the art at the time of invention would have been motivated to employ anticancer agent, asymmetric disulfide taught by Powis in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery system that has the capability of releasing the active ingredient i.e asymmetric disulfide in a controlled rate.

Applicant argues that "as expressly set forth in the specification, the sustained delivery of 1-methylpropyl 2-imidazolyl disulfide resulted in an unexpectedly increased and prolonged decrease in thioredoxin levels." Applicant's arguments with respect to unexpected results herein have been fully considered but are not persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art, since the results are not commensurate with the instant claims. Instant claims are drawn to a composition comprising an asymmetric disulfide, and a matrix which contains at least one polymer. The results provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art because results merely demonstrate the decrease of thioredoxin employing the sustained 3 hour infusion of asymmetric disulfide, 1-methylpropyl 2- imidazolyl disulfide. It is not clear, if the composition employed for the sustained delivery of 1-methylpropyl 2-imidazolyl disulfide contained a polymer. If the polymer was employed in the composition, it is further not clear which polymer was employed. Accordingly, the results does not demonstrate criticality of a claimed range of the compounds i.e 1-methylpropyl 2-imidazolyl disulfide in combination with any polymer in the claimed composition. See MPEP 716.02. Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support of the nonobviousness of the instant claimed invention over prior art.